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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,229	10/27/2006	Selwayan Saini	P08813US00/MP	5464
881 7590 09/20/2007 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER WALLENHORST, MAUREEN	
			ART UNIT	PAPER NUMBER
			1743	
			MAIL DATE	DELIVERY MODE
			09/20/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/562,229

Applicant(s)

SAINI ET AL.

Examiner

Maureen M. Wallenhorst

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/27/06
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_

Art Unit: 1743

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
2. The abstract of the disclosure is objected to because the abstract from the corresponding PCT application should be placed on a separate sheet. Correction is required. See MPEP § 608.01(b).
3. The use of the trademark NAFION has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

4. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since it includes the recitation of the trademark Nafion<sup>TM</sup>. Materials covered by trademarks are not permitted to be recited in claims of U.S. patent applications since these materials are subject to change over time. On lines 7-8 of claim 1, the phrase “the electrochemical outcome” lacks antecedent basis. At the end of claim 1, the phrase “thereby providing an output signal related to the composition of the fluid” is indefinite and vague since it is not clear how this serves to determine the analytes comprising glucose in the body fluid, as recited in the preamble of the claim.

Claim 4 is indefinite since it is not clear whether the “one or more analytes” includes the glucose recited in claim 1.

Art Unit: 1743

On line 2 of claim 7, the phrase “prior to determination” lacks antecedent basis and is indefinite since it is not clear what step of the method recited in independent claim 1 this refers to. Does this “determination” refer to the measurement of the electrochemical outcome recited in claim 1?

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1743

8. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al (US 6,134,461, submitted in the Information Disclosure Statement filed on October 27, 2006) in view of Saini et al (WO 00/20855, also submitted in the IDS filed on October 27, 2006).

Say et al teach of an electrochemical sensor and a method for using the sensor to determine analytes in body fluids such as interstitial fluid and blood. The analytes detected include glucose, lactate or oxygen. The sensor can be used for the in vitro determination of the presence and/or level of an analyte in a body fluid, or can be used for the in vivo determination of an analyte by implantation of the sensor into the arterial or venous system of an individual. The sensor 42 comprises a substrate 50 on which is printed a working electrode 58, a counter electrode 60 and/or at least one reference electrode 62. The electrodes are formed using conductive traces 52 disposed on the substrate 50. A sensing layer 64 is often formed proximate to the working electrode 58 to facilitate the electrochemical detection of the analyte and determination of its level in the sample fluid. A control unit 44 serves to operate the sensor, and a processing unit 45 serves to analyze the measurements from the sensor 42. Say et al teach that an interferent-eliminating layer may be included in the sensor. The interferent-eliminating layer may include a Nafion<sup>TM</sup> material incorporated into a polymeric matrix that is coated over the electrodes. The Nafion<sup>TM</sup> material reduces the permeability of the interferent-eliminating layer to ionic interferents having the same charge as the ionic components to be detected. For example, negatively charged compounds may be incorporated into the interferent-eliminating layer to reduce the permeation of negative species in the body fluid being analyzed. The Nafion<sup>TM</sup> material prevents the penetration of one or more interferents into the region around the working electrode 58. To use the sensor, a body fluid sample is drawn into the sensor using a

Art Unit: 1743

wicking or capillary action so that it contacts the electrodes. A potential is applied across the working and counter electrodes 58, 60 so that an electrical current will flow. The current is a result of the electrolysis of the analyte, and a measurement of the current provides an indication of the level of the analyte in the body fluid sample. See figures 2 and 8, lines 59-66 in column 4, columns 5-6, lines 1-30 in column 7, lines 1-33 in column 22 and lines 38-59 in column 25 of Say et al. Say et al fail to teach that multiple analytes in a body fluid sample can be measured simultaneously using the sensor by applying a varying potential to the electrochemical sensor, and analyzing the resulting electrochemical measurements using a multivariate calibration technique.

Saini et al (WO 00/20855) teach of an electrochemical method for analyzing multiple analytes in a sample simultaneously by using dual pulse staircase voltammetry (DPSV) in combination with an enhanced information recovery technique such as artificial neural networks. In the method, a sample containing multiple analytes such as ethanol, fructose and glucose is applied to an electrochemical sensor having a working, a counter and a reference electrode therein, and an electrode cleaning pulse is applied to the sensor. The first pulse is applied at a relatively high potential to form an oxide layer on the electrode surface, which is then removed, along with any material adsorbed to the electrode, by a negative pulse. A stepwise increasing potential is then applied to the sensor, and current is measured after each step. To facilitate oxide formation and dissolution, analysis is usually performed at a gold or platinum electrode in a solution of relatively low or high pH. The electrochemical response of the mixture is then subjected to virtual separation using a multivariate calibration technique known as an artificial neural network. Saini et al teach that the method involving DPSV followed by data analysis



Art Unit: 1743

using an artificial neural network allows a mixture of aliphatic compounds to be simultaneously measured by yielding a spectra-like response containing numerous peaks corresponding to the different compounds present in the sample. See the abstract, pages 5-6 and 9-10, and the claims in Saini et al.

Based upon the combination of Say et al and Saini et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to apply a varying potential to the electrochemical sensor taught by Say et al followed by an analysis of the resulting data using a multivariate calibration technique such as an artificial neural network since Saini et al teach that the application of a varying potential in incremental steps to a similar type of electrochemical sensor followed by data analysis using an artificial neural network allows multiple analytes in a sample to be simultaneously measured accurately, thus obviating the need for a separate, specialized sensor for each individual type of analyte found within the body fluid sample analyzed using the method of Say et al.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Liamos et al, Heller et al and Feldman et al who all teach of electrochemical sensors for the detection of glucose; Bessant et al who teach of the simultaneous determination of ethanol, fructose and glucose using artificial neural networks; Harrison et al who teach of electrodes in an electrochemical sensor coated with a perfluorosulfonic acid polymer; and Fung et al who teach of a method using dual pulse staircase voltammetry for the simultaneous determination of glucose and fructose.

Art Unit: 1743

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1743

mmw

September 11, 2007

*Maureen M. Wallenhorst*  
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